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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/028,514	02/23/1998	STEPHEN F. GORFIEN	0942.4110002	4800
26111	7590	10/14/2003	EXAMINER	
STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			WARE, DEBORAH K	
			ART UNIT	PAPER NUMBER

1651

DATE MAILED: 10/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/028,514

Applicant(s)

GORFIEN ET AL.

Examiner

Deborah K. Ware

Art Unit

1651

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 25 August 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 25 August 2003. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: of those reasons on the Attachment A.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: None.Claim(s) objected to: None.Claim(s) rejected: 1-3,6-17,20-24,27-37,73-77,140,154 and 157-174.Claim(s) withdrawn from consideration: 79-82,106-109,112,143-153,155 and 156.

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

ATTACHMENT A

The Request for Reconsideration filed August 25, 2003, has been received and considered.

***Claim Rejections - 35 USC § 103***

Applicant's arguments filed August 25, 2003, have been fully considered but they are not persuasive. Shuler et al do teach that pentosan sulfate may be used and does not necessarily require use of dextran sulfate. Furthermore, Shuler discloses that dextran sulfate only works at a specific concentration of 25 ug/ml, note col. 5, lines 40-42. Thus, dextran sulfate would not necessarily been expected to cause aggregation at all concentrations and conditions. Further, it should be noted that the Shuler teaching at col. 12, lines 1-12, referred to by Applicants' Reply filed on November 26, 2002, at pages 10-11, is based on other studies of the background art, and notably Nakashima et al, wherein it was reported that polyanions such as dextran sulfate induce aggregation of mouse lymphocytes. Shuler determined that at specific concentrations dextran sulfate can be an useful polyanion. Also note that insect cells are eucaryotic cell types and considered to be animal cells. Shuler does disclose that dextran sulfate only works at 25 ug/ml thus, one of ordinary skill in the art would have expected dextran sulfate and other polyanions to work and provide successful results for cultivation animal cells in suspension.

Also Shuler is not limited to just dextran sulfate as its polyanion and Shuler does disclose other polyanions such as pentosan sulfate. Therefore, Shuler has been

considered for all it teaches, and Shuler is teaching toward dextran sulfate as well as pentosan sulfate as being used for suspension culturing of animal cells. To culture other animal cells such as mammalian cells is clearly within the purview of an ordinary artisan. To eliminate dextran sulfate is suggested by the art since Shuler does disclose that dextran sulfate can only work at given concentrations and other studies have shown that it can induce aggregation. However, by no means is Shuler teaching away from using dextran sulfate but to the contrary is directing one of skill in the art to its use for suspension culturing to minimize aggregation by controlling its concentration. Chessebeuf et al and Parenteau et al clearly teach mammalian cells. Also Parenteau et al clearly suggest, if not teach, replacing transferrin with ferrous ions and also teach Zn ions and insulin to be useful constituents of separate cell culture media which leads one of ordinary skill in the art to choose optimum replacements for other protein components.

With respect to Applicants' reply and reference to 293 cells that the examiner has not presented any evidence to support that such cells would not have been expected to be cultured any differently from other animal cell lines disclosed in the art and based on knowledge generally available to one of skill in the art, Applicants are directed to their own specification at page 9, lines 1-20 wherein Applicants clearly disclose that these cells are well known in the art. Hence to select for 293 cells is an obvious modification of the prior art in that these cells are well known animal cells and hence would have been expected to be successfully cultured as any other mammalian cells desired to be cultured and as disclosed by Chessebeuf et al and Parenteau et al. Applicants' own

specification serves as supportive documentary evidence for procedure for relying on common knowledge. Therefore, the rejection is deemed proper.

With respect to protein in cell culture medium and that allegations of proteins being well known contaminants are incorrect, however, the cited prior art recognizes such proteins as undefined proteins can interfere with the intended end use of the cells and thus, to eliminate proteins is clearly suggested. Note Parenteau et al at col. 1, lines 15-25. Furthermore, the art clearly teaches the desire to use chemically defined culture media and serum free culture media, note the cited prior art combination, entire disclosures. Parenteau clearly recognizes using Zn additives in absence of insulin and clearly teaches using transferring or ferrous ions. Therefore, one of skill in the art would have expected replacements of proteins with Zinc and iron to provide successful results since the latter are well used in the disclosed media of Parenteau and in the art at large. Also proteins do not always have beneficial qualities in culture media and to the desire to eliminate them is clearly taught in the cited prior art combination.

Thus, for these reasons and those of record the rejection under 35 USC 103 is maintained.

No claims are allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 308-4245. The examiner can normally be reached on 9:30-6:00.

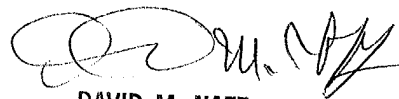
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-0196.

  
Deborah K. Ware  
October 11, 2003

  
DAVID M. NAFF  
PRIMARY EXAMINER  
ART UNIT 12657